

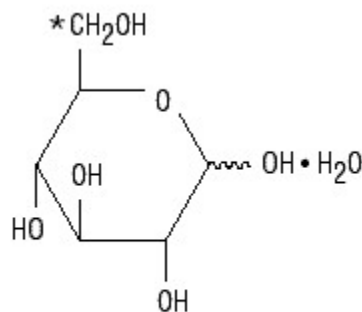
DEXTROSE AND ELECTROLYTE NO. 48 - dextrose monohydrate, sodium lactate, potassium chloride, magnesium chloride, monobasic potassium phosphate and sodium chloride injection, solution

Baxter Healthcare Corporation

in VIAFLEX Plastic Container

DESCRIPTION

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 260 mg Sodium Lactate ($C_3H_5NaO_3$), 141 mg Potassium Chloride, USP (KCl), 31 mg Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$), 20 mg Monobasic Potassium Phosphate, NF (KH_2PO_4), and 12 mg Sodium Chloride, USP (NaCl). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 25 mEq sodium, 20 mEq potassium, 3 mEq magnesium, 24 mEq chloride, 23 mEq lactate and 3 mEq phosphate as HPO_4^- . The osmolarity is 348 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 180 kcal/L.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produce a metabolic alkalizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories or as an alkalizing agent.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

The intravenous administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not for use in the treatment of lactic acidosis.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of these injections to patients receiving corticosteroids or corticotropin.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and electrolytes solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Carcinogenesis and Mutagenesis and Impairment of Fertility

Studies with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Do not administer simultaneously with blood. Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

| <u>Code</u> | <u>Size (mL)</u> | <u>NDC</u> |
|-------------|------------------|------------------|
| 2B2102 | 250 | NDC 0338-0143-02 |
| 2B2103 | 500 | NDC 0338-0143-03 |
| 2B2104 | 1000 | NDC 0338-0143-04 |

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINERS

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn in from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Deerfield, IL 60015 USA

Printed in USA

071947768

07-19-47-768 June 2005

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